Jaw Motion Analysis System

JMA+nalyser

Specifications and Operating Instructions

Inhalt

1 User Notes

1.1 Introduction

Welcome to the User Manual for Jaw Motion Analysis.

This User Manual provides a basic understanding for operating the JMAnalyser+ measuring system for the contact-free analysis of all the 3D movements of the lower jaw, using the method for measuring the travel-time of ultrasound pulses. It explains the basic set-up and operation of the system, and provides tips on preparation for measuring and data acquisition. Technical information on the system and safety precautions can be found in this technical User Manual.

All particulars about the measurement system, in this book, were prepared, compiled, and edited with the greatest of care. Nevertheless, we cannot guarantee that mistakes do not appear. We advise the user that zebris Medical GmbH neither provides a guarantee against, nor accepts any legal responsibility or any liability for consequences resulting from incorrect statements.

The company zebris Medical GmbH does not assume any liability whatsoever for injury to personnel or patients, or damage to the device caused by improper use of the JMAnalyser+ System.

If you notice any mistakes in this manual, or should you have any suggestions for the improvement, we would be very grateful for giving us a short message any time.
In the interests of continuous product development, the manufacturer reserves the right to carry out improvements to this manual and the product described therein at any time and without any further obligation.

Registered trade marks

Several brand names are referred within this User Manual. All these product names are used only for clarityÕs sake or for editorial reasons and are trademarks belonging to the respective companies. When using the brand names, the trade marks them and also the rights of the respective proprietors remain protected.

The name zebris is a registered trade mark and JMAnalyser+ identifies a product of the company, zebris Medical GmbH.

Copyright

1.2 Manufacturer and sales

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1.3 Layout of the user manual for the FDM System

The user manual of the JMAnalyser+ *Jaw Motion System* consists of several parts:

1. JMAnalyser system technical specifications and user manual
2. zebris DENTAL user manual of the application software

The section JMAnalyser Specifications and Operating Instructions and user manual primarily contains information on technical data and the operation of the JMAnalyser system sensor technology as well as on their safe operation. Notes regarding the accessories are limited to essential safety and maintenance measures and hygiene procedures.

WARNING

The exact adherence to the instructions in all sections of the operating Instructions for the measuring system is a precondition for its intended use.

1.4 Conventions and Symbols Used

The green markings in the margin of the User Manual denote new information about the product safety.

ñ**WARNING**ò symbols indicate a potential hazard to the health and safety of the users and/or patients. The warnings describe the risks involved and those can be avoided.

ñ**NOTE**ò symbols indicate a potential risk which could lead to damaging of the device. These NOTE symbols describe the risks involved and how those can be avoided.

The **CE mark** on the type plate confirms the conformity of the measuring system with the Directive 73/23/EEC and Directive 89/366/EEC (Low Voltage Directive and EMC Directive).

The **CE mark with reference number 0535** of notified body BSI (formerly EUROCAT) on the type plate confirms the conformity of the system with the Directive 93/42/EEC for Medical Devices.

Symbol for manufacturer and date of production.

Device of type BF according to DIN EN 60601-1

Symbol for the connection of the external power supply unit (DC voltage 15-20V with indicated polarity)

USB-Interface

The symbol indicates that in accordance with the Directive 2002/96/EEC (Waste Electronic and Electrical Equipment Directive) and national laws, a product must not be disposed of in the household waste, and that within Europe it has to be disposed of in a special way.

Carefully read the accompanying documentation, particularly all information concerning product safety

2 Area of use and safety

2.1 Intended Use

The zebris JMAnalyser system calculates from the recorded jaw movements of the patient all the necessary parameters with the objective of designing a functional prosthesis and splints. The measuring system also allows the output of functional parameters for the programming of virtual and mechanical articulators and export of data for further processing with CAD/CAM or DVT systems.

Furthermore, the system allows the therapeutic positioning of the mandible in a jaw relation.

The measuring system must only be used by trained dentists.

The application environment is limited to dental facilities.

A measurement is performed within 15 minutes, and should not be used on open wounds in the oral and head area, where it may be used in patients of any age who are able to mentally follow the operator instructions exactly.

2.1.1 Use

zebris JMAnalyser systems are electronic registration systems that are based on 3D ultrasound measurements. zebris JMAnalyser systems capture the individual mandibular movements of patients in all degrees of freedom which are necessary for the production of functional dentures and splints.

The 3D representation of the positions and movement traces occlusal or joint near measurement points are particularly important information on the movement behavior of the temporomandibular joint and the lower or upper jaw teeth. The 3D representation of prominent positions in the face is a classification of the symmetry of the face to prepare the denture.

In a preliminary functional assessment discoordinations and movement limitations can be analyzed and documented. The system is able to determine a neuromuscular jaw relation in the situation.

The electronic position analysis of the condyles allows the comparison of different occlusal positions and can thus give indications of possible pain vectors in the joint.

By means of a separate software module, an analysis of chewing movements can be realized.

The system determines the adjustment of fully adjustable virtual or mechanical articulators.

In conjunction with the zebris DAB Bluetooth the JMAnalyser product family enables the analysis of TMJ sounds by means of highly sensitive in the joint area placed borne noise microphones and functional tests of various muscle groups such as temporalis anterior and masseter.

The XML export function allows the use of the determined jaw movements in CAD/CAM systems and CBCT systems for functional optimization of dental restorations and occlusal splints.

The zebris JMAnalyser system is used to support the functional diagnosis. The measuring sensor consists of a receiver and a transmitter. It is attached to the patient's head. The lower jaw sensor is equipped with a special locking mechanism for the attachment. The face bow is put forward by means of support on the nasion and applied to the back of the head above the ears. A measurement can then be carried out, according to the desired settings and measured parameters on the software.

All measuring and analytical results of the zebris JMAnalyser system should always be interpreted in the light of the clinical history of the patient and in the context of other diagnostically methods of a demonstrably trained person and examined for relevance. If invasive measures are taken, the measurement system should only be used as an additional assessment method. Under no circumstances can or should invasive surgery or measures that put the patient at risk be carried out based on the measurement result alone

2.1.2 Articulators

With the help of the zebris JMAnalyser+ system is it possible to adjust the following articulators:

- Artex AR (Girrbach/Amann)
- KaVo PROTAR 7
- SAM
- Stratos 300 (Ivoclar)

2.1.3 Data Export

The XML export function allows the use of determined jaw movements in CAD/CAM systems and CBCT systems for functional optimization of dental restorations and occlusal splints. As a reference for data matching serves a bite fork. This bears reference marks which of imaging systems such as Surface scanner or DVT can be detected.

2.2 Safety

2.2.1 Environmental conditions

The JMAnalyser +jaw motion analysis system is suitable for use in dry interior rooms, as can be found in clinics, medical practices and laboratories.

Temperature range	10°C to 40°C
Relative humidity	30% to 70%

WARNING

The Jaw motion systems must NOT be operated in wet zones, wet rooms (swimming pools, saunas) or climatic chambers.

The measuring systems are not intended for operation in potentially explosive atmospheres of medically used rooms or oxygen-enriched atmospheres.

The devices must not be operated in proximity to e.g. engines or transformers with a high connected load as well as mains current lines, as electrical or magnetic interference fields can falsify correct measurements resp. turn them impossible.

To avoid reciprocal faults from occurring, two SICAT JMT+ systems should never be operated in the same room or near other ultrasound emitting devices (e.g. ultrasonic cleaners, bird scare devices, alarm systems), as this can cause the measured values to be falsified.

2.2.2 Storage and Transport

Storage and transport of the measuring system are only to be effected in the original packaging provided by zebris.

Storage temperature	-20°C to +70°C
Relative humidity	5% to 90%
Air pressure	700 hPa to 1060 hPa

2.2.3 Obligations of the user

- The general guidelines and/or national legislation, national regulations and technical regulations pertaining to medical products are to be applied and fulfilled both with the start-up and during the operation of the zebris product appropriate tot he stated purpose. In Germany, operators, those responsible for such devices, and users are obliged to operate their devices in compliance with the MPG (Medical Devices Act) regulations.
- It is the obligation of the user:
  - ✓ to comply with all the safety instructions stated in the operating instructions.
  - ✓ to carry out all of the inspection and maintenance work regularly as specified in the operating instructions
  - ✓ to only use fault free working equipment.
  - ✓ to ensure all the provided operating instructions that from part of the measurement system, are accessible to all users at all time, and to keep them near the measurement system
  - ✓ to ensure that the device is functionally safe and in a proper stat prior to every instance of use of the device.
  - ✓ to protect oneself, the patients and third parties against dangers.
  - ✓ to prevent a contamination occurring due to the product
- During use, it is necessary to comply with the legal regulations especially:
  - ✓ The current work safety regulations.
  - ✓ The current accident prevention measures.
- Responsibility is assumed to ensure the safety, reliability and effective performance of all measurement systems and accessories delivered by zebris, such that:
  - ✓ assembly work, extensions, new setting, changes or repairs are carried out by zebris authorized, trained technicians or by personnel of authorized dealers. The storage and transport should only be carried out in the original packaging, as provided by the manufacturer.
  - ✓ the product operated in compliance with the operating instructions.
  - ✓ the information technology components provided by the operator comply with the technical requirements for hardware and software contained in these operating instructions, and that they are installed and set up according to the applicable descriptions for these components.
  - ✓ the place of installation corresponds with the specified environmental conditions for the measurement system and the current installation regulations.
  - ✓ Only the software made available by zebris, as well as the components and accesory parts listed in these operating instructions are used with the system.

2.2.4 General safety Information

- The use and operation of the system and the evaluation of measurement data and its interpretation should only be carried out by trained specialist personnel. The manufacturer assumes no liability for damage to persons or property, or the loss of data that may occur due to the improper use of the software, the device, or its accessory parts.
- Patients and measurement data may only be copied, moved or deleted with the help of the database function that is provided by the zebris softwar application. In the case of the deliberate changing of data without the database function, the user alone bears the full risk.
- Measurement and analysis results should always be interpreted in the light of the clinical history of the patient and in the context of other diagnostic tests by a trained person proven and tested for their relevance.
- Should any measures for treatment be taken on the basis of the measuring results, the measuring system may only be implemented as a supplementary means for evaluation by an expert. On no account can, or may invasive measures, or measures endangering the patient be carried out solely on the basis of the measuring results without further verification of the measuring data by additional methods.
- In the case of malfunctions and/or defects being suspected and/or ascertained, the device has to be taken out of use immediately, labeled as ÃOut of Useó, and secured to prevent use. The manufacturer or authorized sales partner must always be contacted in all cases of fault or doubt.
- The measuring system must be checked at regular intervals to make sure it is functioning properly. More details on this can be found in the section, "Maintenance of the Device" in this User Manual.
- Do not install the jaw motion analysis system near a source of heat or in direct sunlight behind a window, as excessive heating can lead to incorrect measurement results.
- Be sure that all the mains and connection cables are laid safely and that they are protected against stepping on, so that nobody can trip over them. Check all the cables and the connection plug regularly for any damage. Damaged power Supplyês and cables have to be replaced before further operation.
- The measurement system is not protected against the penetration of fluids. If fluid penetrates the measurement system, switch it off and please contact the zebris Medical GmbH technical service team.
- Never introduce objects into components of the measurement system.
- Before starting every measurement, it is necessary to ensure the correct choice and correct position of the transmitters or application aids. The cables or the application aids (e.g. Pointer) can present a risk of injury to the patient. In this context, please consult the special instructions in the handbooks of the application software, and do not allow children or mentally impaired patients to enter the proximity of the device without supervision.

2.2.5 Safety information on heart pacemakers/defibrillators

- In the magnetic coupling for the attachment of the lower jaw sensor on the T-attachment there are strong permanent magnets, such as those that are used on headphones on MP3 players. Under especially unfavorable circumstances, at short distances (<15 cm), these magnets can have a negative impact on the functionality of certain implanted heart pacemakers and defibrillators. Therefore, the lower Jaw - sensor should not be positioned on the upper body of the patient on patients with electronic implants.
- Version BT devices contain a Bluetooth transmitter as an interface to the PC. Although there is so far no evidence of a possible interference of heart pacemakers / defibrillators by Bluetooth transmitters, the JMAanalyser+ system is not recommended to be used **on patients with electronic implants using the neck strap, but with the maintaining of a safety distance of at least 15 cm from the patients thorax.**
- No interference of electronic implants is to be expected from the ultrasonic transmitters used in the measurement system, as the JMAnalyser+ system works with airborne sound and very low sound power of a few millimeters. Due to the adverse connection during the transition from the air into the human body, the noise intensity of the measurement signals is weakened strongly such that any interference with implants, as well as any damage to issue, is excluded.

2.2.6 Prohibited Use

- Improper and/or prohibited use of the measurement system is not permitted an express warning is herewith provided of such.
- Do not under any circumstances attempt to maintain or prepare the measurement system in any way other than as described in the operating instructions. This could cause the high sensitivity sensor technology to be in impaired terms of its measurement accuracy
- In the case of malfunctions and/or defects being suspected and/or ascertained, the device has to be taken out of use immediately, labeled as ãOut of Useó and secured to prevent use, with the on/off switch being covered and secured with adhesive tape.
- Changing or modifying the measurement system or its accessory parts without the written permission of zebris Medical is not allowed. If the device is changed without permission, the operator is obliged to carry out suitable examinations and inspections in order to guarantee the secure use.
- zebris measurement systems must not be operated in environmental conditions other than those stated in the ãechnical dataóchapter (e.g. in an oxygen enriched environment, wet zones, damp rooms, climatic chambers, low pressure-,high pressure-, or altitude chambers, etc.).

3 Product description

3.1 System components

In its basic configuration the JMAnalyser+ measuring system consists of the following components:

- JMAnalyser system basic unit
- Lower jaw sensor (Transmitter)
- Head bow (Receiver)
- USB charger for supplying the measurement system for BT devices
- USB cable adapter
- zebris DENTAL application software
- IBM® compatible computer or notebook
- Zubehör (IR-Fernbedienung, Zeigerstift, Kopplungslöffel, Attachments)
- User Manual for system and software, equipment and application software

3.2 Technical data of the JMAnalyser measurement system

Version	JMAnalyser	JMAnalyser BT
REF	1160010	1160015
Dimensions (W x H x D)	145 x 85 x 35 mm	145 x 85 x 35 mm
Weight	160 g	205 g
Power supply	5V DC / 1W (USB)	5V DC / 1W (USB to charge battery)
Battery	no	yes
Measurement range	5 ï 300 mm	5 ï 300 mm
Ultrasonic frequency	40 kHz	40 kHz
Max. measurement rate	50 Hz	50 Hz
Positioning accuracy in the occlusal area	± 0,1 mm (y); ± 0,2 mm (x,z)	± 0,1 mm (y); ± 0,2 mm (x,z)
accuracy articulator angles	± 2,0°	± 2,0°
USB-Schnittstelle	USB mini, USB Standard	USB mini, USB Standard
Bluetooth	no	yes
analog connectors	2	2
analog measurement area	+ 2,5V / resolution of 12 Bit	+ 2,5V / resolution of 12 Bit
analog measurement rate	100/s per canal	100/s per canal

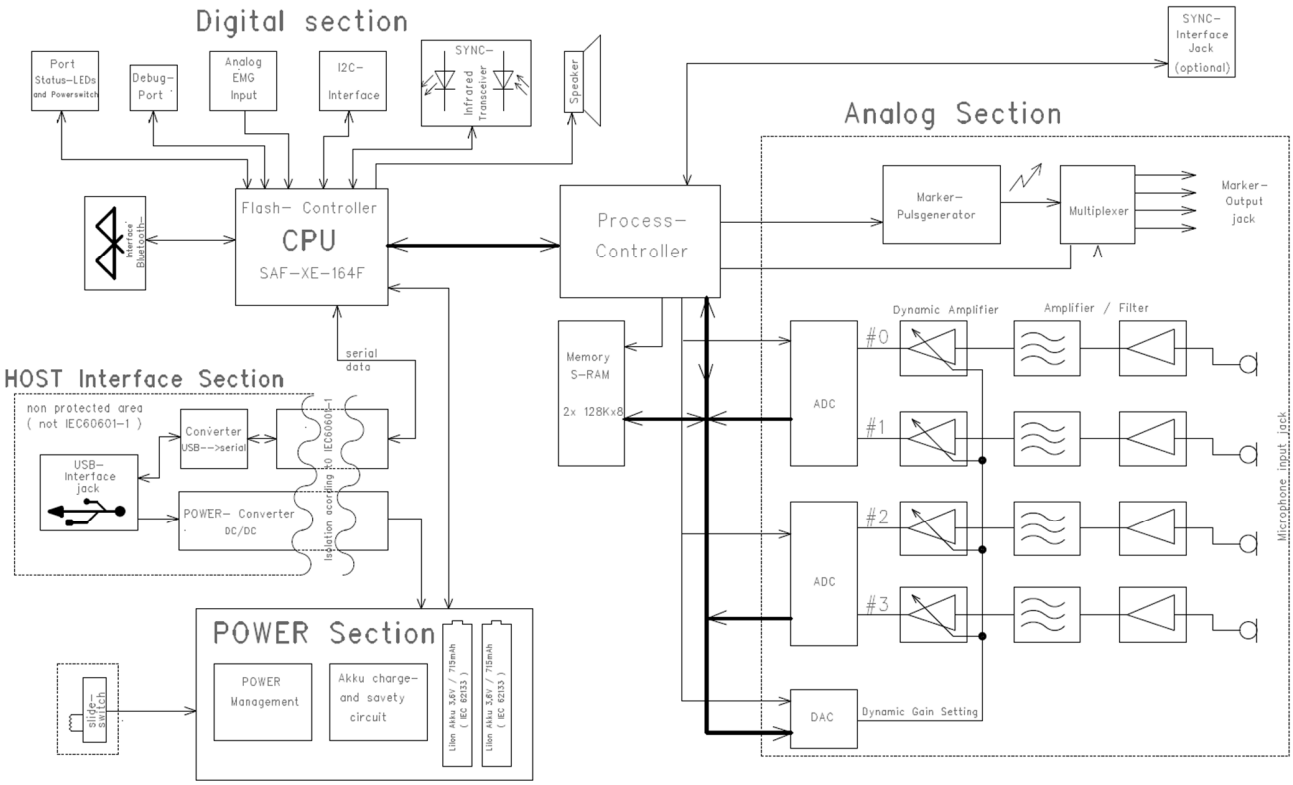
3.3 Measuring principle

The jaw registration system includes the lower jaw sensor and the ultrasonic receiver module at the head bow as well as an foot pedal or an infra-red remote control. The sensory components of the receiver and transmitter modules are mounted in each geometrically defined position. The markers consist of small ultrasonic transmitters which are operated sequentially. The corresponding head bow contains eight ultrasonic microphones. Both modules are connected via a cable to the transmitter in the JMAnalyser measurement system.

In operation, the ultrasonic transmitters provide continuous pulses. From the ultrasonic transit time between the transmitter and receiver microphones, the system calculates by means of an evaluation of a geometry triangulation method, the absolute coordinates of the marker.

The calculation of the measured coordinates and other measurement parameters and the compensation of disturbances are supported by a PC in the evaluation programs.

Block diagram of the measurement system



3.4 Control elements and Connectors

3.5 Meaning of the Display lights

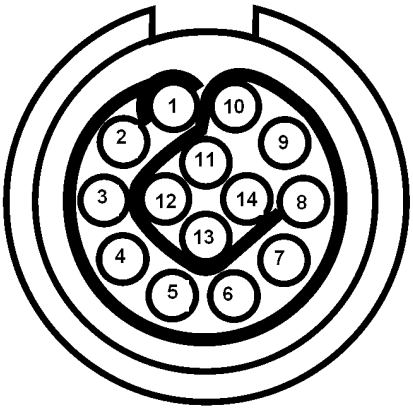
LED	ON/OFF Switch	Meaning
		Green / operational status indicator
off	0 (off)	The measurement system is NOT in operation
lit up	I (on)	The measurement system is in operation
		Orange / measurement
off	I (on)	The measurement system is initializing and ready for measurement.
flashes	I (on)	The measurement system is waiting for initialization, measurement not possible yet.
lit up	I (on)	The measurement has started / ultrasonic transmitters are active.
		Yellow / battery charging status (only JMAnalyser BT)
off	I (on)	USB cable and/or charger connected, reduced charging as soon as charging status > 95%
flashes	0 (off)	USB cable and/or charger connected, battery charging, charging status < 95%
	I (on)	Battery level critical < 20% Connect the USB cable or charger immediately, as it is possible that data will be lost if the measurement is continued.
lit up	0 (off)	USB cable and/or charger connected, battery fully charged, charging status 100%
		Blue / Bluetooth connection (only JMAnalyser BT)
off	I (on)	The measurement system Initializes and is ready for measurement.
lit up	I (on)	The measurement has started / the measurement system is connected with the PC via Bluetooth

3.6 Assignment of the connecting sockets

Foot pedal / digital input (black)

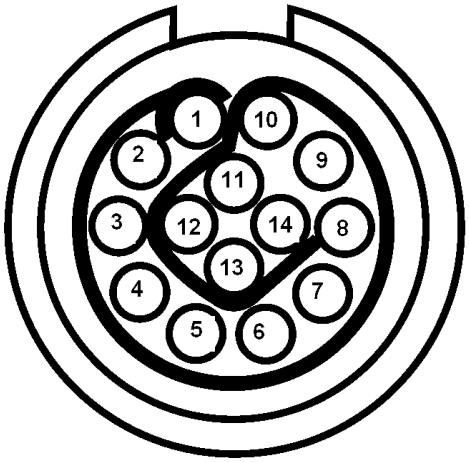
Signal	Pin
GND	Pin 1
BSL_START	Pin 2
+3,3 Volt	Pin 3
n.c.	Pin 4
START_in	Pin 5
n.c.	Pin 6
Dig. Input	Pin 7

Lower jaw Sensor / digital input (light green)



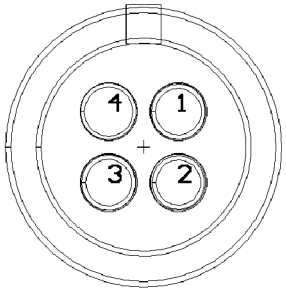
Signal	Pin
Marker 1	Pin 1
Marker 2	Pin 2
Marker 3	Pin 3
Marker 4	Pin 4
SSWBus	Pin 5
n.c.	Pin 6
SDA (I^2C)	Pin 7
SCL (I^2C)	Pin 8
+3,3 Volt	Pin 9
DRY_A	Pin 10
DRY_G	Pin 11
Dig. Input	Pin 12
GND	Pin 13
GND	Pin 14

Head bow / digital input (white)



Signal	Pin
Microphone 1	Pin 1
Microphone 2	Pin 2
Microphone 3	Pin 3
Microphone 4	Pin 4
SSWBus	Pin 5
Mik-Select	Pin 6
SDA (I^2C)	Pin 7
SCL (I^2C)	Pin 8
+3,6 - 12Volt	Pin 9
DRY_A	Pin 10
DRY_G	Pin 11
Dig. Input	Pin 12
GND	Pin 13
GND	Pin 14

analog input (black)



Signal	Pin
Power (+)	Pin 1
Signal	Pin 2
GND	Pin 3
n.c.	Pin 4

3.1 Digital inputs

The measuring system JMAnalyser is equipped in standard specification with an, against reverse polarity protected digital input. It allows digital events such as are transmitted to the application programs from the footswitch.

To activate the inputs they are connected to the ground provided on each terminal.

Input resistance	10 KΩ (pull-up)
V_{IH} (High-Level Input Voltage)	> 2,0V
V_{IL} (Low-Level Input Voltage)	< 0,8V
Min. signal duration in order to cause a triggering	1mS

The digital input is set to +5V (Ä1ñ) with an internal pull-up resistor. By pulling this input up to 0V (Ä0ñ) through a switch, relay contact or similar, the input is triggered.

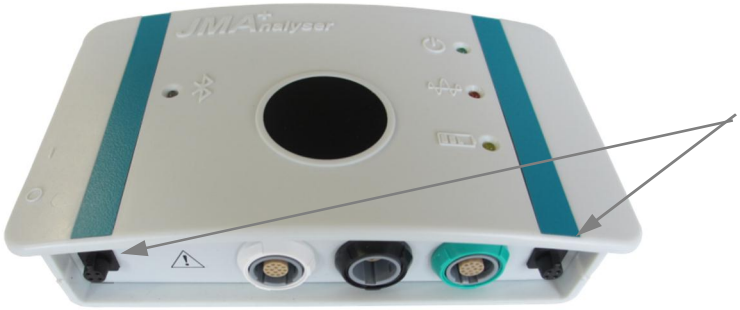
3.2 EMG for the determination of the muscle tone of the jaw muscles

For the synchronous recording of the EMG data, zebris offers EMG differential electrodes amplifier cables as an accessory that are optimally adjusted to the JMAnalyser system:

REF: 126.0031 / EMG-DENTAL2N amplifier

REF: 126.0041 / EMG-DENTAL2 amplifier

The EMG differential electrodes amplifier cables are directly connected to the JMAnalyser system and thanks to their particularly small electrode contacts are particularly suitable for the use in dental medicine. The EMG data is evaluated in envelopes. Please find further notes on the application of the EMG module in the zebris DENTAL software manual.



Technical specifications analogue inputs

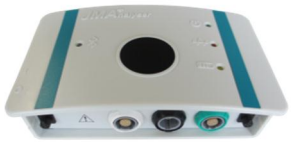
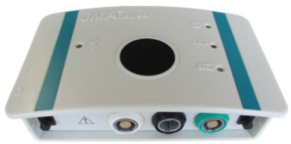
Input resistance	10E + 12 Ω
CMRR	110 dB
Noise referring to the input signal	0.28 µV pp
Bandwidth	7 Hz to 500Hz
Output voltage	power supply -1 V

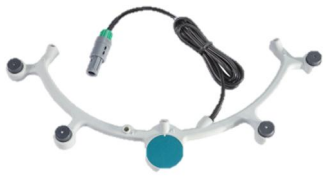
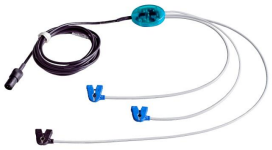
WARNING

The EMG double electrodes (REF 810.0020) are not reusable and intended for single use only.

If other EMG electrodes are used than those recommended by zebris, the user shall bear sole responsibility for their biological compatibility.

3.3 Accessories and spare parts

REF-No.	Description	Illustrations
116.0010	**JMAnalyser basic unit** for direct connection with USB interface	
116.0015	**JMAnalyser BT basic unit** for battery operation with Bluetooth interface	
126.0010	**Head bow type 14R** for measurement systems JMAnalyser and JMA-nalyser BT With all application parts	
196.0130	**Nasion support** fitting for all zebris head bows	
196.0140	**Bearing seat** fitting for all zebris head bows	
196.0012	**Bearing cushion green** for bearing seat 196.0140 packaging unit 5 pieces	
196.0013	**Nose cushion green** packaging unit 5 pieces	
196.0014	**Elastic neckband green** packaging unit 5 pieces	
1860420	**USB adapter for JMAnalyer+** For connection to the PC	

REF-No.	Description	Illustrations
196.0112	**Headband green**	
196.0092	**Lanyard green**	
146.0010	**Lower jaw Sensor type 14T** for measuring systems JMAnalyser and JMAnalyser BT	
191.0025	**pointer 80** medical steel, sterilize able length 80mm, ball aperture 1,5 mm	
196.0260	**Para-occlusal attachment 90** for the fixation on the front teeth L = 60 mm / W = 90 mm, medical steel, sterilize able	
196.0271	**occlusal adapter** for the fixation of the lower jaw sensor at the occlusal attachment medical steel, sterilize able, length =60mm	
196.0270	**occlusal attachment** made from LEXAN, suitable for gas and steam sterilization Hint: single use item, not intended for multiple use	
196.0320	**bite fork type SD** made from LEXAN, suitable for gas and steam sterilization Hint: single use item, not intended for multiple use	
196.0400	**Bite for adapter** for attachment of the LJ-sensor to the bite fork	
126.0031	**EMG-DENTAL2N amplifier** With N electrode, amplification 1000, particularly small electrode contacts, especially suitable for the use in dental medicine.	

REF-No.	Description	Illustrations
126.0041	**EMG-DENTAL2N amplifier** Without N electrode, amplification 1000, particularly small electrode contacts, especially suitable for the use in dental medicine.	
810.0020	**EMG double electrodes** 1 pack à 25x8 pieces Note: For single use only, not designed for reuse.	
181.0702	**Foot pedal** for measuring systems JMAnalyser and JMAnalyser BT	
186.0010	**IR- remote control** for all JMAnalyser-Messsysteme	
3310.1110	**USBpower supply unit with country adapter** For charging JMAnalyser BT	
3310.1115 3310.1117 3310.1116 3310.1118 3310.1119	**EU - Adapter USB power supply unit** **UK - Adapter USB power supply unit** **USA - Adapter USB power supply unit** **Australia - Adapter USB power supply** **World - Adapter USB power supply**	
800.0510	**USB cable A-B, 3m long** Data connection of measurement system and PC	
800.0220	**Bluetooth USB-Stick** mit Plug and Play Funktion	
720.0001	**zebris DENTAL Software** for operation system Windows 7 32/64 Bit Download of Updates from zebris Service Center: http://www.zebris.de/deutsch/extranet/	
890.0510	**User Manual** Printing version is liable to be charged. Free download of PDF-Files from zebris Service Center: http://www.zebris.de/deutsch/extranet/	

4 Putting the measurement system into operation

For the commissioning of the jaw motion analysis system, a USB cable of type A to Mini-B, as well as the installation CD is required with the JMAnalyser+ application software. All components are included in the scope of delivery for the JMAnalyser+ system.

4.1 Power supply and charging the battery (only JMAnalyser BT)

For the rapid charging of the battery of the SICAT JMT+ measurement system when it is in the deactivated state, connect the charger with an AC outlet and a USB cable of type A to Mini-B with the Mini-USB socket on the measurement system.
Alternatively, the measurement system can also be charged or operated directly on the USB socket of a PC. To do this, connect the PC directly using a USB cable (type A to B or type A to Mini-B).

WARNING	Only connect the USB charger that is approved and supplied by SICAT, and arrange the measurement system such that the plug for the power socket is easily accessible at all times and the device can be easily disconnected from the mains.

USB charging power supply / REF 3310.1110

NOTE	Before connecting the charger to the mains, consult the name plate information on the power supply unit, checking that the voltage and frequency is consistent with the local data. Only connect if such consistency is given.

WARNING	Carry out a full visual inspection to the power supply unit, power cable and plug, as well as the protective contacts before the connection and/or operation of the measurement system. Damaged power supply units, cables or plug connectors must be replaced immediately by an authorized person.

4.2 Computer requirements

As a rule, the measuring system JMAnalyser is supplied together with a computer. If the system is to be operated using other computers or components, the user must then inquire whether the intended coupling guarantees the necessary safety for the test person, the operator and the surroundings by consulting the manufacturer, the authorized zebris sales partner or by asking a specialist.

Please refer to the zebris DENTAL Software Manual for informations according to PC requirements.

WARNING

If the computer is not supplied with the measuring system, the manufacturer shall not be held liable for any damage or malfunctions arising from a faulty coupling. Should additional hardware be built into the computer or software installed, the manufacturer shall not be liable for any malfunctions or damage occurring.

The computer must be CE marked and fulfil the requirements of DIN EN 60950 resp. DIN EN 60601-1.

WARNING

The JMAnalyser measuring system is not designed for the operation within a network/data network. The connection of the system with a networtk/data network can cause unforeseen risks for patients or third parties. If the zebris DENTAL software shall be installed in a network/data network, the operator is obliged to determine, analyse, evaluate and control the risks that are connected with doing so ï particularly with regard to the aspects data protection, virus security, updates of the operating system and regular backups. Risk considerations have to include subsequent changes of the network/data network, like e.g. update/upgrade of devices and components that are connected to the network.

4.3 Installing the zebris DENTAL software

If your measuring system is delivered without PC/laptop, please install the application software before connecting the measuring system to the computer. Please find information on the installation in the user manual of the zebris DENTAL software.


NOTE

Please make absolutely sure that you have installed the zebris software before connecting the JMAnalyser system to the computer using the USB cable.

If the platform is connected without installing the software before, problems when installing the device driver may occur and the system does not work, for the Windows operating system registered in the initial connection of the JMAnalyser system and the PC the location of the driver on the hard disk.

If no corresponding zebris software installed on the PC yet, the mapping of the driver will fail for the above reasons, and the JMAnalyser system may not function correctly.


NOTE

How to solve problems with the hardware driver

Should problems with the hardware driver of the JMAnalyser system occur then disconnect the platform from the PC and restart it. Now proceed with installing the zebris DENTAL software another time and reconnect the platform when the installation procedure has been finalized.

4.4 Connecting the accessory Parts

Connect the head bow,lower jaw sensor and possible foot switch with the corresponding colored socket on the measurement system.

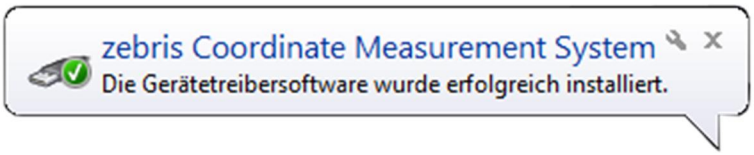

NOTE

Bitte beachten Sie beim Anschluss von Kopfbogen, UK-Sensor und Fußschalter an das Messsystem, dass die Stecker mittels Kodier-Nasen gegen Verpolung bzw. Einstecken in der falschen Buchse geschützt sind. Alle Stecker sollten stets leichtgängig und ohne größere Krafteinwirkung in die Buchsen gleiten.

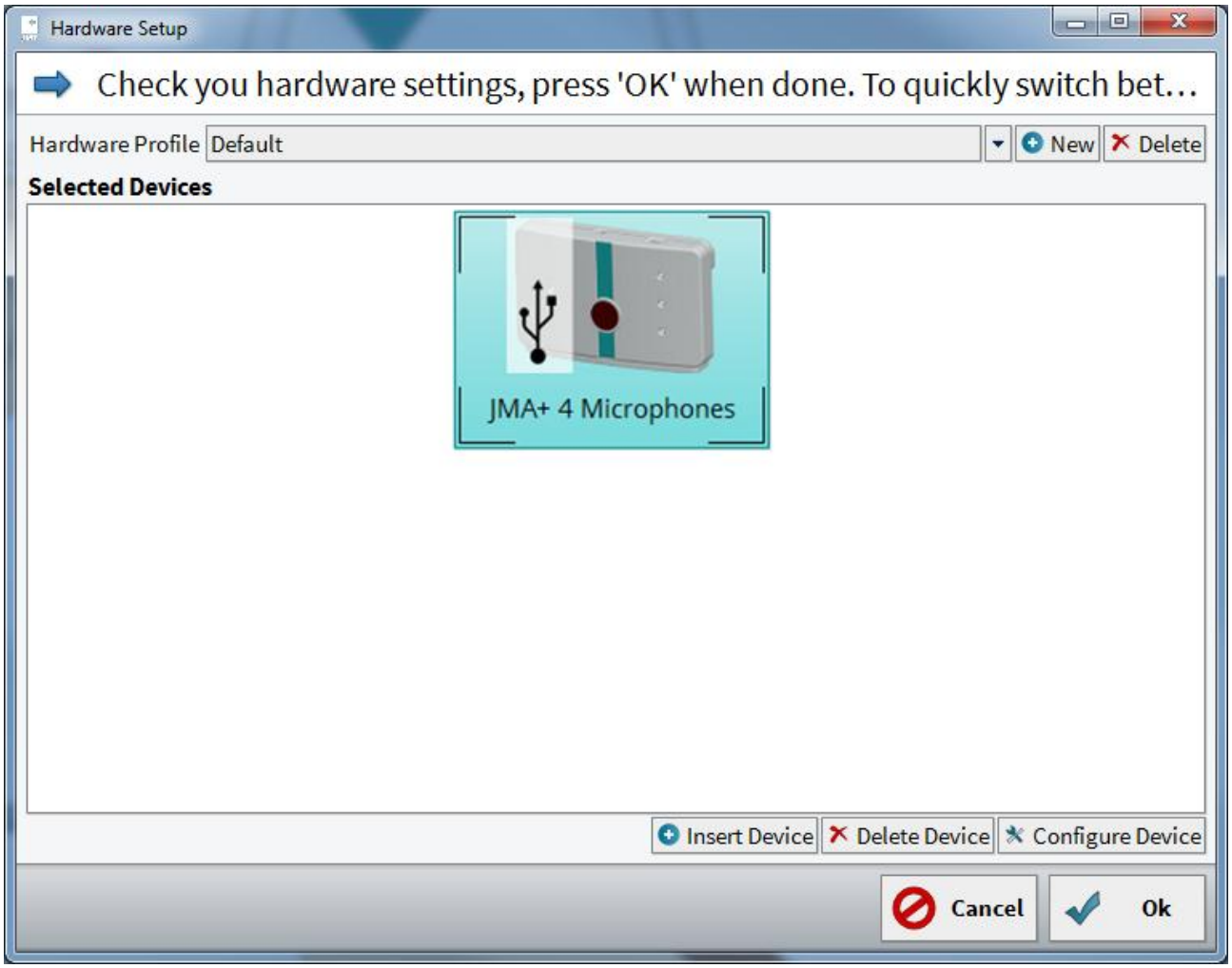
Next, connect the measurement system and a USB interface on your computer with the USB cable provided, or set up the Bluetooth connection. In this context, it is necessary to ensure that the measurement system is switched on. Your measurement system is now ready to use. Detailed instructions on the operation of the JMAnalyser+ system are provided in the operating instructions for the zebris DENTAL software.

4.5 Connection of the basic unit via USB Interface

If the measuring system is operated via USB interface, the device is automatically recognized by the zebris DENTAL software. Wait until the hardware installation process has finished and the following massage appears.



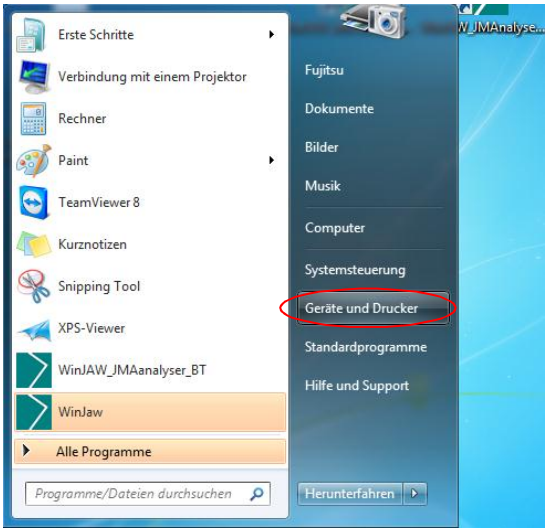
Now the measuring system is ready for use and can be found in the software under device settings.



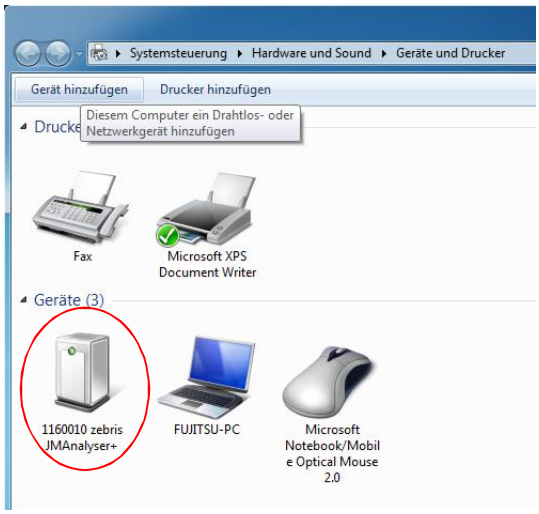
For more information on installation please refer to the operating instructions for zebris DENTAL Software.

4.6 Connection of the basic unit via Bluetooth interface

Select the ñStartò button on the desktop and then select "Devices and printers".



Under ñControl Panelò > ñDevices and Printersò you will find the button ñAdd deviceò.Through the recognition of the ñ1160015 zebris ***JMAnalyser*** òthis device can now be paired with your PC and added to the bluetooth capable systems.



When clicking on the ***JMAnalyser*** symbol, it is highlighted. Click on the symbol again with the left mouse button and select ñSettingsñ under the section ñServicesñ, so that the following system configuration information is read out.

In addition, the ñCOM portò for the ***JMAnalyser*** **BT** to which the device is connected has to be selected within the device settings. This one can be found, as described under ñPC settings with ***JMAnalyser*** **BT** ò, in the system configuration. Confirm by clicking ñOKò. The operational readiness of the device is confirmed through the flashing blue bluetooth LED.

4.7 Taking the measurement system out of operation

To take the measurement system out of operation, please start by connecting the SICAT JMT+ software, shutting the PC down, and switching it off. Next, switch the SICAT JMT+ measurement system off and decouple the USB connection from the PC or charger. Next, unplug the charger from the socket.

5 Control measures, Preparation, Disposal

- Scheduled maintenance of the system is essential in order to prevent damage and guarantees the safety of the device. All methods concerning the systemûs maintenance and disinfection mentioned in this user manual should be carried out on a regular basis.
- Should any malfunctions and/or defects be determined or suspected, the device must be put out of operation immediately, marked as "Out Of Service" and prevented from being used by removing the mains cable. In such case be sure to contact the manufacturer or an authorized sales partner.
- The maintenance of the device or its accessories, going beyond the procedures described in this user manual, must exclusively be carried out by zebris Medical GmbH or a person who has been explicitly authorized by zebris to do this.
- Be sure to switch of the measuring system and disconnect it from mains supply before starting any maintenance work.

5.1 Mandatory periodic inspections and STK

- The zebris Medical GmbH does not stipulate any safety-related control for the JMAnalyser system.
- For maintaining the correct state of the electrical equipment, checks and technical safety inspections have to be carried out repeatedly (e.g. within Germany, acc. to BGV A3, and accident prevention regulations and technical safety tests according to the Medical Device Operating Regulations). Here it should be noted that standard regulations for electrical devices are concerned here and not measures that are specific to zebris.
- For safety reasons it is recommended before each use of the measuring system, to check the correct state of all the connection leads, as well as the mains cable, mains plug and mains socket. Should certain parts be damaged, these must be replaced before continuing to use the measuring system.
- Immediate maintenance measures are to be carried out if:

  a) Fluid enters the device
  b) Cable or cable connections have been damaged
  c) Parts of the sensors were damaged
  d) Covers have been damaged
  e) A malfunction or a fault is suspected or has been detected

- If the type plate or other important labels (warning notices) are damaged or obliterated they have to be replaced by the manufacturer for safety reasons.

5.2 Checking the measurement function

WARNING

To guarantee long-term patient safety, the SICAT JMT+ system has to be inspected at regular intervals to ensure its proper measurement function. After hard knocks, such as if the head bow or LJ-sensor should fall on the floor, it is necessary to check the measurement function immediately. In the event of evident damage to system components (warping, dents, cracks), no further measurements should be carried out.

- The ultrasonic transmitters of the lower jaw sensor can be inspected for this function during a measurement by listening to see whether a regular cracking is emitted from each of the transmitters.
- To inspect the system, for known jaw function measurements (e.g. known maximum opening width, known condylar range of motion with protrusion, known horizontal condylar guidance inclination), the user can measure himself with the measurement system. These measurement results should correspond with the known values.
- When the sensors do not move, the zebris DENTAL software should show an unmoving image of the lower jaw. Possible deviations (spikes or jumps in the measurement curve in spite of unmoved markers, incorrect presentation of the lower jaw, etc.) indicate a faulty measurement and impair the evaluation
- Should doubts surround the measurement accuracy, inspecting the JMAnalyser system at zebris is recommended in order o ensure the stated measurement accuracy.

5.3 Troubleshooting

Please check the following points if technical malfunctions should occur:

- ✓ Is the JMAnalyser system switched on and being supplied with electricity? (green operating display LED is lit on the measurement system, batteries are charged or charger and/or USB cable is connected)
- ✓ Has the USB connection and/or Bluetooth connection between the measurement system and measuring PC been made correctly?
- ✓ Are all the other components in the measurements system (head bow, lower jaw sensor, foot pedal) connected correctly?

NOTE

Please find further information on error messages and troubleshooting in the user manual of the zebris DENTAL software.

Checklist for the reception of error messages

NOTE

In order to support you the best way possible in case of malfunction of your JMAnalyser measuring system, our service employees need the following information:

- ✓ Serial number of the JMAnalyser System and the lower jaw sensor/head bow

  The serial numbers are on the name plates on the rear of the measurement system and/or on the cables for the head bow and lower jaw sensor
- ✓ zebris DENTAL software version
- ✓ Operating system version of your measurement PC

  e.g. Windows 7 Professional Service pack 1
  (to find under Windows 7: Windows Start button → Control Panel → System)
- ✓ Further components connected to the measurement system

  zebris DAB-Bluetooth, Video-Kamera
- ✓ List of all USB/Bluetooth devices connected to the measurement system

  e.g. mouse, printer, other measuring systems, etc.
- ✓ Screen shot of the error message, or exact wording

  e.g. ÄTimeout reading from USBñ
- ✓ Precise and detailed description of the procedure that has led to the error message.

  e.g. Measurement ñType Aò started, then clicked on button ñBò, afterwards carried out movement ñCò, switched to function ñDò, when switching back, the error message xyz occurred etc.

5.4 Preparation Methods

NOTE	After every case of use of the JMAnalyser+ system, a re-preparation is required according to DIN EN ISO 17664. All accessory parts that come into contact with the patient's mucosa have to be sterilized before use.
WARNING	Before starting cleaning work or disinfection, switch the measurement system off under all circumstances and disconnect it completely from the power supply network.

The following accessory parts are only intended for one-off use on a patient, and should not be prepared again after use.

- Occlusale attachment (REF 196.0270)
- Bitefork type SD (REF 196.0320)
- EMG double electrode (REF 810.0020)

5.4.1 Manual cleaning

- Before sterilization, clean the accessory parts by hand under running water (drinking water quality, 30°C ± 5 °C, flow rate 2 liters/min.) with a medium strength toothbrush for 30 seconds.
- Complete the sterilization immediately subsequent to the cleaning
- The cleaning of measurement systems and electrical accessories (head bow, lower jaw sensor, foot pedal, IR remote control) should only be carried out when the system is switched off and the charger and/or USB cable are unplugged, and using a damp cloth.

5.4.2 Manual disinfection

The measurement system can be wipe-disinfected with suitable solutions. Disinfect all components with a cloth that has been dampened with a disinfection solution.

WARNING

No spray disinfection!

Spray disinfection can destroy the highly precise measurement sensors of the platform.

Recommended disinfection agent

Composition approx. 25% ethanol, 35% Propanol
E.g. Mikrozid Liquid / Schülke & Mayr or similar agents

NOTE

If you apply disinfection agent be sure to follow the recommendations given by the manufacturer of the disinfection agent strictly. Especially consider the rules concerning the commended application time of the agent.

WARNING

Due to danger of confusion, chemicals that are necessary for the disinfection or cleansing exclusively must be stored, prepared and provided in containers that are appropriate for this purpose.

5.4.3 Sterilization

All accessory parts that come into contact with the patientôs mucosa have to be sterilized before use.

NOTE

The sterilization its o be completed immediately subsequent to the cleaning.

Sterilize the bite-fork and lower jaw attachment with a fractionated pre-vacuum for four minutes at 134 °C and 3.04 bar (can be sterilized up to max. of 138 °C).

It is necessary to sterilize the following accessory parts:

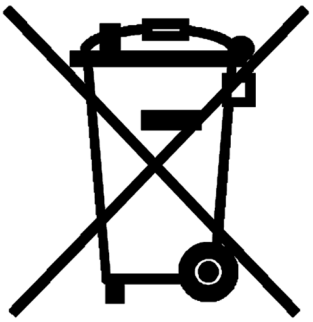
- Para-occlusal attachment 90 (REF 196.0260)
- Occlusal adapter (REF 196.0271)
- Occlusal attachment (REF 196.0270)
- Biteforke type SD (REF 196.0320)

5.6 Disposal

5.6.1 Packaging

All transport packagings delivered by zebris can be recycled within Germany via the local recycling depots. In order to provide the reuse of the recyclable material contained in the packaging, the zebris Medical GmbH takes part in the dual ZENTEK system that takes over the proper disposal of packaging.

5.6.2 Disposal of electronics



This symbol states that according to the directive on waste electrical and electronic equipment (2012/19/EEC) the product must not be disposed by means of the domestic waste system. Within Europe this device must be forwarded to a specific waste disposal system.

Therefore regular disposal is carried out by the manufacturer. For this purpose the system should be shipped to the manufacturer and will be forwarded to regular disposal by zebris.

The improper interaction with electronic waste could lead to negative effects for the environment and the public health because of potential hazardous materials which are frequently contained within electric and electronic devices. Additionally with the proper disposal of this product you will contribute to the effective use of natural resources.

Accumulators and batteries

Accumulators and batteries must not be disposed of with domestic waste! In the interest of environmental protection, the consumer is legally obliged (battery regulation) to return old and used batteries. Used accumulators and batteries can be disposed of at the collecting points of the community or where batteries of the relevant kind are sold. For consumers, the batteries are taken back free of charge.

6 Safety standards and system classification

6.1 Classification acc. to Annex IX of Directive 93/42/EEC

The system is then classified as medical product **Class I with measuring function**.

6.2 Safety of medical electrical devices

The device fulfils the requirements of the standard DIN EN 60601-1:2006.

Classification according to DIN EN 60601-1

Type BF

Safety class II

Steady state conditions

Unsuitable for use in an oxygen-enriched atmosphere

6.2.1 Connecting the JMAnalyser - system to other electrical devices

(Quod vide DIN EN 60601-1:2006 section 16 medical electrical systems)

WARNING

The JMAnalyser System may only be coupled with other electrical devices if these conform to the provisions of DIN EN 60950 or DIN EN 60601-1 or zebris Medical GmbH has confirmed their compatibility.

WARNING

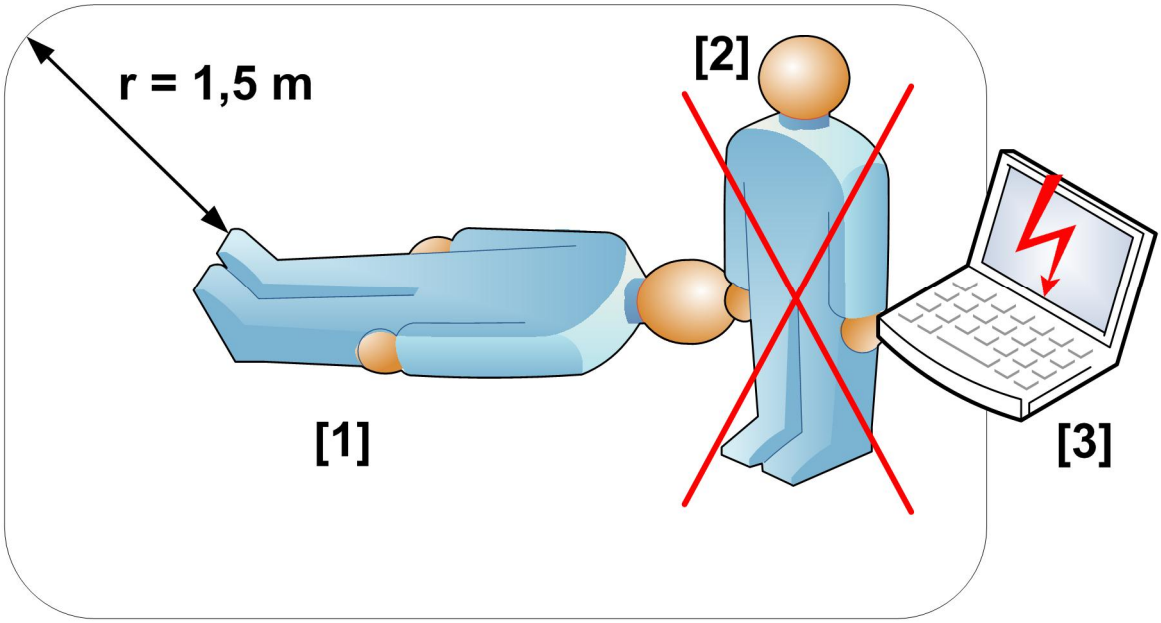
When coupling several devices to one measuring station, please note that no danger through summation of leakage currents can occur.

Devices that are in direct contact with the patient and that are commonly used in a medical electrical system, as a whole have to fulfil all requirements of DIN EN 60601-1:2006 section 11.

There is a danger of electric shock when touching devices that are not grounded separately.

6.2.2 Vicinity of the patient / test person

For the definition of the patientôs surroundings, experience shows that a value of 1,5 m distance to the patient is optimal.



WARNING

When operating the system, the user [2] must ensure that he does not touch the PC [3] and the patient [1] at the same time. The same applies for all other non-medical, electrical components; they may only be used outside the patient's vicinity.

Furthermore, the user must ensure, never to touch the contacts of the connectors of the interface box and the patient at the same time.

In case of non-observance, dangerous leakage currents can occur.

The following components of the JMAnalyser system may be used in the vicinity of the patient:

- JMAnalyser including sensor technology
- zebris Measuring Systems for medical purposes (e.g. CMS20, DAB Bluetooth)

WARNING

The computer and other non-medical electrical equipment (e.g. camera equipment, lights) have to be located beyond the reach of the patients (1.5m).

6.3 Electromagnetic compatibility Guideline & Manufacturer Declaration

The JMAnalyser+ system satisfies the requirements of the EN 60601-1-2 standard. (Medical electrical devices ï part 1-2: General concerning for safety including the key performance attributes ï supplementary norm: Electromagnetic compatibility ï requirements and tests).

Inspecting authority: SCHWILLE ï ELEKTRONIK
Produktions- und Vertriebs GmbH
Benzstrasse 1A
85551 Kirchheim

Detailed information on EMC values and information supplied by the manufacturer can be found in the tables in this Section of the User Manual.

Electrical equipment in the medical field is subject to particular precautionary measures as regards the EMC (Electromagnetic Compatibility) and must be installed and put into operation in accordance with the instructions given below.


WARNING

Even though the motion analysis system JMAnalyser fully complies with the requirements of the standard EN 60601-1 it cannot be totally excepted that portable and mobile RF communications equipment can affect the system. If ever possible such devices should not be operated within the system environment during measurements


WARNING

The use of accessories, particularly cables for connecting to the PC, that are not supplied by zebris for use with the JMAnalyser system, or explicitly recommended for use with the device, can lead to a reduced resistance to EMC interference of the JMAnalyser system.


WARNING

The JMAnalyser measuring system should not be operated in the vicinity of e.g. X-ray equipment, motors or transformers with a high connected load, as electrical or magnetic interference fields can influence the measurements. The same is applicable for neighbouring power lines and equipment without a CE mark. Should operation next to possible sources of interferences be necessary it is mandatory to check and verify the correct function of the system.

Guidelines and Manufacturer's Statement - Electromagnetic Emission		
The JMAnalyser jaw motion measuring system is intended for use in the electromagnetic environment described below. The customer or user of the JMAnalyser jaw motion measuring system should ensure that it is operated in such an environment.		
Emitted interference measurements	**Compliance**	**Electromagnetic environment guidelines**
RF emissions acc. to CISPR 11	Group 1	The JMAnalyser jaw motion measuring system uses RF energy exclusively for its internal functions. Therefore its RF emission is very low and it is unlikely that electronic equipment in close proximity will experience interference.
RF emissions acc. to CISPR 11	class B	The JMAnalyser jaw motion measuring system is intended for use in all facilities including those in residential areas and those directly connected to a public utility network also supplying buildings used for residential purposes.
Emission of harmonic oscillations acc. to IEC 61000-3-2	class B	
Emission of voltage fluctuations / flickers acc. to IEC61000-3-3	in compliance	

Guidelines and Manufacturer's Statement - Electromagnetic Interference Immunity			
The JMAnalyser jaw motion measuring system is intended for use in the electromagnetic environment described below. The customer or user of the JMAnalyser jaw motion measuring system should ensure that it is operated in such an environment.			
Interference immunity tests	**IEC 60601 test levels**	**Compliance level**	**Electromagnetic environment guidelines**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV atmospheric discharge	± 6 kV contact discharge ± 8 kV atmospheric discharge	Flooring should be of wood or concrete or laid with ceramic tiles. If the flooring is made of synthetic material, the relative humidity must be at least 30%.
Fast transient electrical interferences/bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Blackouts, brownouts and fluctuations of the power supply acc. to IEC 61000-4-11	< 5% U_T (> 95% crash of the U_T) for ½ period 40% U_T (60% crash of the U_T) for 5 periods 70% U_T (30% crash of the U_T) for 25 periods < 5% U_T (> 95% crash of the U_T) for 5 s	< 5% U_T (> 95% crash of the U_T) for ½ period 40% U_T (60% crash of the U_T) for 5 periods 70% U_T (30% crash of the U_T) for 25 periods < 5% U_T (> 95% crash of the U_T) for 5 s	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment. If the user of the JMAnalyser jaw motion measuring system requires the continuation of functionality also after power interruptions/disruptions, it is recommended to provide the JMAnalyser jaw motion measuring system with power from an uninterruptible power supply.
Magnetic field with supply frequency (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	Not tested as no influence is possible on the device within the specified test level. (see Note B)	Magnetic fields of the mains power frequency should comply with the typical values of a business and hospital environment.
NOTE U_T is the AC main voltage prior to applying the test levels.			

Guidelines and Manufacturer's Statement - Electromagnetic Interference Immunity

The JMAnalyser jaw motion measuring system is intended for use in the electromagnetic environment described below. The customer or user of the JMAnalyser jaw motion measuring system should ensure that it is operated in such an environment.

Interference immunity tests	**IEC 60601 test levels**	**Compliance level**	**Electromagnetic environment guidelines**
			Portable and mobile wireless sets should not be used in closer proximity to the JMAnalyser jaw motion measuring system, including the cables, than the recommended safety distance, that is calculated on the basis of the formula suitable for the transmitting frequency. **Recommended safety distance:**
Conducted RF interference quantities acc. to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d = 1.2\sqrt{P}$
Radiated RF interference quantities acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			With *P* as the rated output of the transmitter in watts (W) according to the information provided by the manufacturer of the transmitter und *d* as the recommended safety distance in meters (m). The field strength from fixed RF transmitters as determined by an electromagnetic site survey [a] is less than the compliance level [b] in all the frequencies. Interference is possible in the proximity of devices featuring the following pictograph

NOTE 1 The higher value applies in the case of 80 MHz and 800 MHz

NOTE 2 These guidelines may not be applicable in all situations. The spread of electromagnetic waves is influenced by absorption and the reflections of buildings, objects, and people

a The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile services, ham radio stations, AM and FM radio and TV broadcasters is theoretically not 100% predictable. A site study is recommended to determine the electromagnetic environment as a result of stationary RF transmitters. If the measured field strength at the site of the FDM-T force distribution measuring system exceeds the compliance levels listed above, the FDM-T force distribution measuring system must be monitored to document its proper functionality at every place of application. Additional measures might become necessary, e.g. modifying the orientation or moving the location of the JMAnalyser jaw motion measuring system, if unusual performance characteristics are observed.

b The field strength is less than 3 V/m for the frequency range of 150 kHz to 80 MHz

Recommended Safety Distances between Portable and Mobile RF Telecommunications Devices and the JMAnalyser jaw motion measuring system

The JMAnalyser jaw motion measuring system is intended for use in an electromagnetic environment where RF interference quantities are controlled. The customer or user of the JMAnalyser jaw motion measuring system can contribute towards preventing electromagnetic emissions by complying with the minimum distance between portable and mobile RF telecommunications devices (transmitters) and the JMAnalyser jaw motion measuring system, as recommended below in accordance with the maximum output power of the communication device.

Rated output of the transmitter (W)	**Safety distance based on the transmitting frequency (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The safety distance for transmitters with a rated output not listed in the table above, can be calculated by applying the formula corresponding to the respective column, whereby P is the rated output of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1 For calculating the recommended safety distance of transmitters in the frequency range of 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to reduce the probability of a mobile/portable telecommunications device taken unintentionally into the patient's area, causing interference.

NOTE 2 These guidelines may not be applicable in all situations. The spread of electromagnetic waves is influenced by absorption and the reflections of buildings, objects, and people.

6.4 Konformitätserklärung

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

zebris Medical GmbH

Hersteller / manufacturer	**zebris Medical GmbH** Max-Eyth Weg 43 88316 Isny Deutschland / Germany

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

das Medizinprodukt / the medical device	**zebris Dental – Kiefer-Bewegungsanalysesystem** **zebris Dental – Jaw-Motionanalyser System**
Modell/Typ / Model/Type	**JMAnalyser+, JMAnalyser+ BT** **JMT+, JMT+ BT**
UMDNS Nummer / UMDNS Code	**15-845**
Klassifizierung / classification	**Im**
nach Regel / according to rule	**12**

den Anforderungen der unten genannten Richtlinien / Normen soweit anwendbar entspricht.
meets all the provisions of directives and standards listed below which apply to it.

Konformitätsbewertungsverfahren nach / conformity assessment procedure acc.	**Richtlinie 93/42/EWG Anhang V** geändert durch Richtlinie 2007/47/EWG **Directive 93/42/EEC Annex V** amended by Directive 2007/47/EEC

Angewandte harmonisierteNormen / Applied harmonised standards	**DIN EN 1041** **DIN EN 1640** **DIN EN 7405** **DIN EN 13485** **DIN EN 14971** **DIN EN 15223-1**	**DIN EN 60601-1** **DIN EN 60601-1-2** **DIN EN 60601-2-40** **DIN EN 62304** **DIN EN 62366**

Diese Konformitätserklärung gilt für alle oben gelisteten Medizinprodukte welche am oder nach dem Ausgabedatum von zebris hergestellt worden sind. Die Gültigkeit dieser Konformitätserklärung endet mit der Veröffentlichung einer Konformitätserklärung neueren Datums, falls dies durch technische Änderungen am Produkt oder durch Änderungen von Richtlinien oder Normen erfolgen muss, spätestens jedoch mit Ablauf des CE-Zertifikats nach Richtlinie 93/42/EWG mit Nr. CE 573437.

This declaration of conformity is valid for all medical devices listed above which have been manufactured by zebris at or after the date of issue. The validity of this declaration expires with the release of a new declaration due to technical or legal amendments – however latest at the expiry date of the CE-certificate according to directive 93/42/EEC with certificate number CE 573437.

D-88316 Isny, 13.012.2013

Wolfgang Brunner
Geschäftsführer / Managing Director
zebris Medical GmbH

Benannte Stelle / Notified Body:
BSI Group Deutschland GmbH
D-60314 Frankfurt am Main

CE 0535

File: N:\03_Produkte_Hardware\zebris_Dental\10_Zulassung\10_Konformitätserklärung\Declaration_Conformity_zebris_Dental_Annex_V_131213.docx Page 1/1

7 Note